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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,290	02/25/2002	Masaaki Kosaka	350292001300	1521

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/069,290

Applicant(s)

KOSAKA ET AL.

Examiner

Jegatheesan Seharaseyon, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/27/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. This office action is in response to the amendment and remarks filed on 8/4/05. Applicant has cancelled claim 1. Therefore, claims 2-8 are currently pending.
2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.
4. The Office acknowledges the receipt of translated priority documents.
5. The Office also acknowledges the IDS submitted 6/27/2005.
6. Applicant's arguments filed 8/4/05 have been fully considered but they are not deemed to be persuasive.

#### ***Claim Rejections - 35 USC § 102***

7. The rejection of claim 1 under 35 USC 102(b) as being anticipated by Arora et al. (1998) or Bungard et al. (1998) is withdrawn because Applicants have cancelled the claim.

#### ***Claim Rejections - 35 USC § 103***

8. The rejection of claims 2-8 under 35 U.S.C. 103(a) as being unpatentable over Ozaki et al (1997) in view of Bungard et al. (1998) and Koishihara et al. (U. S. Patent. No: 6, 503, 510) is maintained for reasons indicated in the Office Action dated 2/4/2005 and argued further below. Applicants argue that Ozaki et al. reference does not teach the use of interferon- $\alpha$  and interferon- $\gamma$  in combination with anti-HM 1.24 Moab. It is also argued by the Applicants that Bungard et al. does not show the use of interferon- $\alpha$  and

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interferon- $\gamma$  for enhancing antibody-dependent cell-mediated cytotoxicity (ADCC).

Therefore, Applicants assert that there is no motivation to use cytokines for increasing ADC activity. Finally, Applicants argue that Koishihara reference fails to disclose administering interferon- $\alpha$  and interferon- $\gamma$  in combination with the claimed antibody or any motivation for administering this claimed combination.

Applicant's arguments have been fully considered but have not been found to be persuasive. Although, Ozaki et al. does not recite the use of specific cytokines in combination with anti-HM 1.24 Moab, it does teach that the "administration of cytokines, such as IL-2, IL-10, IL-12, macrophage colony-stimulating factor (M-CSF), has been shown to increase the levels of ADCC by the stimulation of effector cells, suggesting the combinations of these cytokines along with the antibody to further potentiate the effect of the antibody support" (p. 3185, 2<sup>nd</sup> paragraph). Thus enhancing the therapeutic effect of the claimed agent.

Ozaki et al. is cited as teaching the same antibody used by Applicant and Applicant has not argued that the antibody taught by Ozaki et al. is different. Ozaki et al. need not teach a combination of the antibodies along with interferon- $\alpha$  and interferon- $\gamma$ ; such is taught by Bungard et al. Finally, Koishihara et al. (U. S. Patent. No: 6, 503, 510) describes anti-HM1.24 antibody that has cytotoxic activity that binds to SEQ ID NO: 2 of the instant invention (see column 3 lines 1-17). One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response

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to applicant's argument that there is no motivation provided by Bungard or Koishihara to combine the references, as was stated in the previous Office Action, Bungard et al.

teaches that ADCC of mAb 17-1A and the mAb BR55-2 against colorectal carcinoma is enhanced by the treatment of cytokines including interferon- $\alpha$ , interferon- $\gamma$  and IL-2.

Contrary to Applicants assertion that there is no teaching to indicate that there is ADCC, Figure 2 clearly indicates that the addition of mAb BR55-2 to PBMC and one of the cytokines resulted in even more pronounced elimination of tumor cells compared to the incubation with PBMC and cytokine alone (page 215, 2<sup>nd</sup> paragraph). Koishihara et al. describes anti-HM1.24 antibody as a therapeutic agent that has cytotoxic activity and binds to SEQ ID NO: 2 of the instant invention. Ozaki et al. teaches the increase in the levels of ADCC by the stimulation of effector cells, suggesting the combination of these cytokines along with the antibody anti-HM 1.24 Moab in treating myeloma. Thus it would be obvious to the artisan of ordinary skill to combine them, resulting in therapeutic agents for myeloma. Furthermore, the courts have held that:

Specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY 1979); and In re Burckel 201 USPQ 67 (CCPA 1979).

and

In considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968).

and

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it is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Ozaki teaches anti-HM 1.24 antibodies inhibit tumor growth. In addition, it discloses that the administration of cytokines has been shown to increase the levels of ADCC by the stimulation of effector cells, suggesting the combination of these cytokines along with the antibody further potentiate the effect of the antibody. Bungard et al. have showed that ADCC of specific antibodies against tumor is enhanced by the treatment with cytokines including interferon- $\alpha$ , interferon- $\gamma$  and IL-2. Thus the combination of Ozaki, Bungard and Koishihara suggests to the artisan of ordinary skill a therapeutic agent comprising an antibody along with interferon- $\alpha$ , and interferon- $\gamma$ .

9. NO CLAIM IS ALLOWED.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 10/05

  
**JANET L. ANDRES**  
**SUPERVISORY PATENT EXAMINER**